

## REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 6, 12, 13, and 18 are currently being amended. Support for the new claim can be found, at least, in the specification as filed, e.g., page 10, lines 9-13, page 15, lines 16-18, page 19, lines 12-16, the figures, e.g., figures 2a, 2b, 2c, 4, 5, 8, and 9, and the claims as filed, e.g., claim 11. No new matter has been added.

Claims 24-27 are being added. Support for the new claims can be found, at least, in the specification as filed, e.g., page 10, lines 9-13, page 15, lines 16-18, page 19, lines 12-16, the figures, e.g., figures 2a, 2b, 2c, 4, 5, 8, and 9, and the claims as filed, e.g., claims 6 and 11. No new matter has been added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-27 are now pending in this application.

## **Examiner Interview Summary**

Applicant thanks Examiner Christopher Koharski for the telephonic examiner interview on December 31, 2008. During the interview, the applicant and the examiner discussed the independent claims 1, 12, and 18 in view of the references cited in the Office Action dated 09/12/2008. In particular, the applicant and the examiner discussed Mericle (U.S. Patent No. 4,214,586) and Matkovich (U.S. Patent No. 5,810,398). During the interview, the examiner suggested claim limitations directed towards the position of the elements of the connection elements. The applicant has amended the independent claims 1, 12, and 18 substantially based on the examiner's suggested claim limitations. As such, applicant believes that the claims 1-24, as now amended, are now in a condition for allowance.

### **Objection**

The Office Action objected to claim 18 because of an informality regarding the reference numerals. Claim 18 has been amended to correct the informality regarding the reference numerals. As such, claim 18, as now amended, is in a condition for allowance, and the objection to claim 18 should be withdrawn.

### **Rejections Under 35 U.S.C. § 112**

The Office Action rejected claims 13-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. In particular, the claim element “weakened area” lacks antecedent basis in the claims. Claim 13 has been amended to correct the antecedent basis in claims 13 and 14. As such, claims 13-14, as now amended, are in a condition for allowance, and the rejection to claims 13-14 should be withdrawn.

### **Rejections Under 35 U.S.C. § 102**

1. The Office Action rejected claims 1-6, 8, 11-12, and 15-16 under 35 U.S.C. 102(b) as being anticipated by Mericle (U.S. Patent No. 4,214,586). Applicant respectfully disagrees with this rejection.

In some embodiments, the present application is directed to “[a] connection assembly for transferring a fluid, particularly a fluid containing active products, from a reservoir to a medical delivery device,” as presented in claim 1, as now amended, of the present application. The connection assembly comprises a first connection element and a second connection element. The first connection element comprising first retaining means and a reservoir interface. The second connection element comprising second retaining means and a medical delivery interface. The connection assembly further comprises “at least one of the first and second connection elements comprises a perforator, which is reversibly connectable to standard connectors allowing fluid transfer therethrough before an irreversible connection is made with the other element, the

respective retaining means is positioned between the perforator and the respective interface.” Independent claims 12 and 18, as now amended, are similarly presented.

Mericle describes “[a] three-piece anastomotic coupling device for end-to-end anastomosis of tubular members consisting of two open bore cylindrical adaptors and an open bore cylindrical connector.” (Mericle: Abstract, see Figure 4). The adaptors in Mericle include a plurality of annular ridges 13 which circumscribe the outer circumference of an area of the adaptor and a single annular recess 14 which circumscribes the conical section to form a locking ridge 15. (Mericle: col. 2, lines 49-57, see Figure 1). The connector in Mericle includes locking appendages 18 and guiding appendages 19. (Mericle: col. 2, lines 58-68, see Figure 2). In operation, the three-piece anastomotic coupling device described in Mericle is assembled by inserting the adaptors 10 “into connector 16 until locking appendages 18 engage annular recess 14 in the adaptor, at which time ridge 21 of appendage 18 abuts ridge 15 of the adaptor locking the adaptor securely in place.” (Mericle: col. 3, lines 11-20, see Figure 4).

Mericle does not describe “at least one of the first and second connection elements comprises a perforator, which is reversibly connectable to standard connectors allowing fluid transfer therethrough before an irreversible connection is made with the other element, the respective retaining means is positioned between the perforator and the respective interface,” at least, for the following reasons.

First, Mericle describes the adaptors and the connector being securely locked in place for the transfer of any fluid and not any type of perforator that is reversibly connected to standard connectors. Even if the ends 14 and 15 of the adaptors as described in Mericle could be utilized as reversible connectors as set forth on pages 3-4 in the Office Action dated Sept. 12, 2008, the ends 14 and 15 in Mericle do not include a perforator that is reversibly connected to standard connectors and retaining means that are positioned between the perforator and the respective interface. Furthermore, even if the ends 14 and 15 of the adaptors of Mericle are considered as the perforators then there would not be a retaining means positioned between the perforator and the interface since the ends 14 and 15 would be the interfaces into the reservoir and/or medical

delivery device. As such, Mericle does not describe a perforator that is reversibly connected to standard connectors before an irreversible connection.

Second, Mericle describes two cylindrical adaptors and an open connector that form the coupling device and not the first and second connection elements being irreversibly connected together to allow for the transfer of fluid between the reservoir and the medical delivery device. In other words, Mericle describes a coupling device that has three parts, two adaptors and a connector, and not a connection assembly with a first and second connection elements.

As such, claims 1-6, 8, 11-12, and 15-16, as now amended, are now in a condition for allowance, and Applicant respectfully requests the withdrawal of the rejection of claims 1-6, 8, 11-12, and 15-16. Furthermore, new claims 24-27, which depend directly from independent claim 1 are also in a condition for allowance based, at least, on their dependency from claim 1 and their distinctions over the cited prior art.

2. The Office Action rejected claim 18 under 35 U.S.C. 102(b) as being anticipated by Matkovich (U.S. Patent No. 5,810,398). Applicant respectfully disagrees with this rejection.

Matkovich does not describe “(i) reversibly connecting at least one of a first connection element associated with the reservoir and a second connection element associated with the medical delivery device to respective standard connectors via a perforator allowing fluid transfer therethrough before an irreversible connection is made with the other connecting element,” “(ii) translating the first connection element having a first retaining means and a reservoir interface relative to the second connection element having a second retaining means and a medical delivery device interface, the respective retaining means is positioned between the perforator and the respective interface” or “(iii) irreversibly connecting together the translated first and second connection elements through cooperation of the first and second retaining means,” at least, for the following reasons.

First, in addressing a retaining means, Matkovich recites “any coupling...which locks or becomes non-separable after coupling.” (Matkovich: column 15, line 66 - column 16, line 1).

Following coupling, Matkovich describes the coupled unit, where “the advance of the stem is sufficient to allow the stem to pierce...the sealing layer of each membrane assembly...[with] the head, which comprises a piercing element.” (Matkovich: column 13, lines 35-39). Matkovich provides an irreversible coupling process that precedes a process to puncture the seals of the connection elements. As a result, no material can be transferred to the connection elements before the irreversible connection is made. Matkovich does not allow for a prior reversible coupling, nor would it have been obvious, as any attempt to do so would break a connection element seal and contaminate the sterile field of the connection element, in direct opposition to the teachings of Matkovich.

Second, Matkovich describes a connector assembly with two connectors 100 and 200. (Matkovich: abstract, col. 4, lines 21-23, see Figure 1). Each connector 100 and 200 in Matkovich includes a fitting 130 and 230, a membrane assembly 170 and 270, and tubing 10 and 20, which provides for fluid communication into the connector assembly. (Matkovich: col. 5, lines 14-21, col. 6, lines 5-7, see Figure 1). As described above, the connectors 100 and 200 are fitted together in Matkovich to form the connector assembly and the piercing element is utilized to pierce the sealing layer of each membrane assembly to allow for the fluid flow between the connectors.

Matkovich does not describe “reversibly connecting at least one of a first connection element associated with the reservoir and a second connection element associated with the medical delivery device to respective standard connectors via a perforator allowing fluid transfer therethrough before an irreversible connection is made with the other connecting element.” Rather, as described in Matkovich, since the fluid flow cannot be made through the membrane assembly until after the piercing element is utilized to pierce the sealing layer of the membrane assembly and the irreversible coupling process precedes the piercing, then the piercing element in Matkovich cannot be used for the reversible connection since the piercing element is not exposed until after the irreversible connection is made to maintain the sterility of the connector assembly.

Furthermore, even if the tubing 10 and 20 in Matkovich is considered to be the reversible connections as set forth on page 4 in the Office Action dated Sept. 12, 2008, then Matkovich does not describe that the reversible connection is made via the perforator or that “the respective retaining means is positioned between the perforator and the respective interface.” Matkovich does not describe that the tubing is any sort of perforator. In contrast, the piercing element in Matkovich is the element that pierces the membrane assembly and not the tubing. Furthermore, in this configuration of Matkovich, the perforator would interface with the outside sources of fluid (e.g., reservoir, medical delivery device, etc.) and not the respective interface since the perforator and the respective interface would have to be on different sides of the connector. In addition, in this configuration, any such respective retaining means in Matkovich would not be positioned between the perforator and the respective interface, but would be positioned on either side of such perforator or respective interface.

As such, claim 18, as now amended, is now in a condition for allowance, and Applicant respectfully requests the withdrawal of the rejection of claim 18.

### **Rejections Under 35 U.S.C. § 103**

1. The Office Action rejected claims 9 and 17 under 35 U.S.C. 103(a) as being unpatentable over Mericle in view of Erskine et al. (U.S. Patent No. 5,820,614). Applicant respectfully disagrees with this rejection.

Mericle is discussed above. As such, a discussion of Mericle is not repeated herein.

Erskine describes a disconnect device for placement in medical tubing. (Erskine: abstract, see Figure 3a). The disconnect device in Erskine includes two portions and each portion includes a valve for shutting off fluid communication. (Erskine: abstract, see Figure 3a). Erskine does not describe “at least one of the first and second connection elements comprises a perforator, which is reversibly connectable to standard connectors allowing fluid transfer therethrough before an irreversible connection is made with the other element, the respective retaining means is positioned between the perforator and the respective interface.” Rather,

Erskine describes a disconnect device that eliminates “potentially lethal incidents by disconnecting the tubing with an application of force that is less than the force that would potentially physically disrupt the medical access device.” (Erskine: col. 2, lines 52-55). In other words, Erskine does not describes a connector for a reversible and then an irreversible connection, but instead describes a disconnect device that minimizes the safety risk involved with fluid communication.

Neither Merice or Erskine, combined or separately, describe, teach, or suggest, the claim limitations of claims 9 and 17. As such, claims 9 and 17, as now amended and based on their dependency from claim 1, are now in a condition for allowance, and Applicant respectfully requests the withdrawal of the rejection of claims 9 and 17.

2. The Office Action rejected claims 10, 13-14, and 19-23 under 35 U.S.C. 103(a) as being unpatentable over Mericle or Matkovich in view of Folden (U.S. Patent No. 5,221,267). Applicant respectfully disagrees with this rejection.

Mericle is discussed above. As such, a discussion of Mericle is not repeated herein.

Matkovich is discussed above. As such, a discussion of Matkovich is not repeated herein.

Folden describes a breakable tubing coupling that is a hollow cylindrical element insertable into the lumens of distal and proximal sections of a fluid delivery tubing system and the breakable tubing coupling can be broken and separated by application of a bending force. (Folden: abstract, see Figure 2). Folden does not describe “at least one of the first and second connection elements comprises a perforator, which is reversibly connectable to standard connectors allowing fluid transfer therethrough before an irreversible connection is made with the other element, the respective retaining means is positioned between the perforator and the respective interface.” Rather, Folden a breakable tubing coupling that is inserted inside a tubing system. In other words, Folden does not describes a connector for a reversible and then an irreversible connection, but instead describes a coupling that is easily broken by bending without

the need for scissor or a knife or that the delivery line will be cut on the wrong side of the clamp. (Folden: col. 4, lines 35-41).

None of the cited references, Merice, Matkovich, or Erskine, combined or separately, describe, teach, or suggest, the claim limitations of claims 10, 13-14, and 19-23. As such, claims 10, 13-14, and 19-23, as now amended and based on their dependency from independent claims 1 and 18, respectively, are now in a condition for allowance, and Applicant respectfully requests the withdrawal of the rejection of claims 10, 13-14, and 19-23.

3. The Office Action rejected claim 7 under 35 U.S.C. 103(a) as being unpatentable over Mericle. Applicant respectfully disagrees with this rejection.

Mericle is discussed above. As such, a discussion of Mericle is not repeated herein.

Mericle does not describe, teach, or suggest the claim limitations of claim 7. Based on the above discussion of Mericle and its dependency from claim 1, claim 7, as now amended, is now in a condition for allowance, and Applicant respectfully requests the withdrawal of the rejection of claim 7.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.


The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of



papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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